

REMARKS/ARGUMENTS

Claims 1-3, 5-7, 9-42, 44-53, 56-57 and 203-204 are currently pending in the application. Claims 1-3, 5-7, 9-42, 44-53, 56-57 and 203-204 were rejected in the Office Action mailed August 14, 2008 (hereinafter referred to as "Office Action"). A three-month extension of time to respond to this Office Action and a credit card authorization are being submitted herewith. Applicant respectfully submits that this response is timely filed on Tuesday, February 17, 2009 because the extended due date of February 14, 2009 fell on a Saturday and the following Monday, February 16, 2009 was a USPTO holiday (Presidents Day). In view of the following remarks and amendments, applicant respectfully requests a timely Notice of Allowance be issued in this case.

Claim Objections

Claims 18 and 19 were objected to because of the phrase "wherein the of two or more genes." (page 2, lines 14-page 3, line 4). Applicant respectfully submits that claims 18-19 have been amended to add the term "dataset." Applicant respectfully requests reconsideration and withdrawal of the objections to claims 18-19.

Claim Rejections under 35 U.S.C. § 101

Claims 1-3, 5-7, 9-42, 44-53, 56-57 and 203-204 were rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. More specifically, the Office Action stated that "the claimed invention involves mathematical algorithm" (page 3, line 14), and "there is not physical transformation by the claimed invention" (page 4, line 4). With respect to claims 1-3, 5-7, 9-42, 44-53 and 56-57, the Office Action stated that these claims "do not produce a tangible final result" (page 4, line 19) because "[t]here is no guarantee that a user will have access to the electronic file, or understand the data encoded on the electronic file" (page 5, lines 2-3). With respect to claims 203-204, the Office Action stated that a "computer readable medium" can include a data signal embodied in a carrier wave which is a nonstatutory natural phenomena. (page 5, line 14-page 6, line 6).

Applicant respectfully submits that the proper test to determine whether a claim is drawn to a patent-eligible subject matter under Section 101 is the machine-or-transformation test. *See In re Bilski*, 545 F.3d 943, 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008). Applicant respectfully submits that claims 1-3, 5-7, 9-42, 44-53, 56-57 and 203-204, as amended, satisfy the machine-or-transformation test and are, therefore, allowable under 35 U.S.C. § 101.

Claims 1

The Office Action indicated that "[t]his rejection could be overcome by amendment of the claims to recite that a specific final result of the process is outputted to a user." (page 5, lines 6-8). Applicant respectfully submits that claim 1 has been amended to recite that the identified locations of the single nucleotide polymorphisms in the nucleic acid sequence where single nucleotide polymorphisms will likely occur (the specific final result) are ***output to a user via a***

computer display, an electronic file or a printer. (emphasis added). Moreover, applicant respectfully submits that claim 1, as amended, satisfies the transformation test because the raw data is transformed into a visual depiction to a user via a computer display, an electronic file or a printer. *See In re Bilski*, 545 F.3d 943, 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008); *In re Abele*, 684 F.2d 902, 908-09 (CCPA 1982). Accordingly, applicant respectfully submits that claim 1, as amended, satisfies the machine-or-transformation test and is, therefore, allowable under 35 U.S.C. § 101. Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 1.

Claim 2-3, 5-7, 9-42, 44-53 and 56-57

Applicant respectfully submits that claims 2-3, 5-7, 9-42, 44-53 and 56-57 depend from claim 1, which is allowable for the reasons stated above. Claims 2-3, 5-7, 9-42, 44-53 and 56-57 are, therefore, allowable under 35 U.S.C. § 101. Accordingly, applicant respectfully requests reconsideration and withdrawal of the rejection of claim 2-3, 5-7, 9-42, 44-53 and 56-57.

Claims 203-204

Applicant respectfully submits that the computer-readable medium as recited in claims 203-204, as amended, is structurally and functionally interrelated to the medium and is statutory because the use of technology (“executable by a processor”) permits the function of the descriptive material to be realized. *See* Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (Annex IV, paragraph 2). In other words, “[a] computer readable medium encoded with a computer program executable by a processor for predicting one or more locations . . .” is functional descriptive material. Note that MPEP § 2106.01(i) states that “***a claimed computer-readable medium encoded with a computer program is a computer element*** which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, ***and is thus statutory.***” (emphasis added). The computer program, as recited in the claims, is part of a computer that is executable by the computer's processor, so the claim is directed to part of a machine (i.e., a processor of a computer). *See In re Bilski*, 545 F.3d 943, 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008). Accordingly, applicant respectfully submits that claims 203-204, as amended, satisfy the machine-or-transformation test and are, therefore, allowable under 35 U.S.C. § 101. Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 203-204.

Claim Rejections under 35 U.S.C. § 102

Claims 1, 45 and 46 were rejected under 35 U.S.C. § 102(b) as being anticipated by Shapiro, et al. (hereafter referred to as Shapiro) in view of *Journal of Immunology*, 1999, 163, 259-268. For anticipation, a single reference ***must identically disclose every element*** of the claimed invention. *Corning Glass Works v. Sumitomo Electric*, 9 USPQ 2d 1962, 1965 (Fed. Cir. 1989). A reference that excludes a claimed element, no matter how insubstantial or obvious, is enough to negate anticipation. *Connell v. Sears, Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983). Applicant respectfully submits that claims 1, 45 and 46 are not anticipated by Shapiro and are, therefore, allowable under 35 U.S.C. § 102(b) for the reasons stated below.

Claim 1

First, applicant respectfully submits that Shapiro does not identically disclose “calculating a variation frequency ***from a first base to a second base*** within a group of bases in a dataset of two or more genes” as recited in claim 1. (emphasis added). As shown in Tables I-III, Shapiro discloses a mutability index for dinucleotides (Tables I and III) and trinucleotides (Tables II and III) for a first base, but does not disclose or take into consideration what the second base is. In other words, Shapiro calculates a mutability index for the first base without regard for what the second base is. As a result, applicant respectfully submits that Shapiro ***does not identically disclose*** every element of the claimed invention as required by 35 U.S.C. § 102.

Second, applicant respectfully submits that Shapiro does not identically disclose “generating a variation predictiveness matrix from the calculated variation frequency ***for each first base to each second base***” as recited in claim 1. (emphasis added). As shown in Tables I-III, Shapiro discloses a mutability index for dinucleotides (Tables I and III) and trinucleotides (Tables II and III) for a first base, but does not disclose or take into consideration what the second base is. In addition, Table III in Shapiro can be said to disclose a matrix, but the matrix is based on the position within the dinucleotide or trinucleotide. In other words, Shapiro’s matrix is based on the position within the dinucleotide or trinucleotide without regard for what the second base is. As a result, applicant respectfully submits that Shapiro ***does not identically disclose*** every element of the claimed invention as required by 35 U.S.C. § 102.

Third, applicant respectfully submits that Shapiro does not identically disclose “comparing the ***nucleic acid sequence which is not obtained from the dataset of two or more genes***, one or more bases in the nucleic acid sequence at a time, with the variation predictiveness matrix to assign a variation value to the one or more bases in the nucleic acid sequence” as recited in claim 1. (emphasis added). As discussed above, the claimed variation predictiveness matrix is not identical to any matrix disclosed in Shapiro. In addition, Shapiro appears to be directed at one dataset at a time containing known mutations (page 260, Sequence Sources; Figures 1-7; Tables I-III) in order to determine whether “all Ig genes in mice and humans mutate by a common mechanism and that di- and trinucleotide sequence composition alone can predict regional mutation patterns, but in a nonquantitative manner” (page 260, left column, lines 14-17; Tables I-III). Applicant respectfully submits Shapiro does not use a variation predictiveness matrix determined for a dataset to analyze a nucleic acid sequence which is not obtained from that same dataset. As a result, applicant respectfully submits that Shapiro ***does not identically disclose*** every element of the claimed invention as required by 35 U.S.C. § 102.

Fourth, applicant respectfully submits that Shapiro does not identically disclose “***identifying the locations of the one or more bases in the nucleic acid sequence where single nucleotide polymorphisms will likely occur*** based on the assigned variation value” or “outputting the ***identified locations of the single nucleotide polymorphisms in the nucleic acid sequence where single nucleotide polymorphisms will likely occur*** to a user via a computer display, an electronic file or a printer” as recited in claim 1. (emphasis added). As discussed above, Shapiro appears to analyze one data set at a time. Moreover, Shapiro only discloses mutability indexes

and regional mutability (Tables I-III; Figures 3-6). Applicant respectfully submits that regional mutability is not identical to identifying the **locations of bases** where single nucleotide polymorphisms will likely occur. As a result, applicant respectfully submits that Shapiro **does not identically disclose** every element of the claimed invention as required by 35 U.S.C. § 102.

For at least these reasons, Shapiro **does not identically disclose** every element of the claimed invention. Accordingly, applicant respectfully submits that claim 1 is not anticipated by Shapiro and is, therefore, allowable under 35 U.S.C. § 102(b). Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 1.

Claims 45 and 46

Applicant respectfully submits that claims 45-46 depend from claim 1, which is allowable for the reasons stated above, and further distinguish over the cited references. Claims 45-46 are, therefore, allowable under 35 U.S.C. § 102(b). Accordingly, applicant respectfully requests reconsideration and withdrawal of the rejection of claims 45-46.

Claim Rejections under 35 U.S.C. § 103(a)

Claims 2-3, 5-7, 9, 10 and 37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shapiro in view of *Journal of Immunology*, 1999, 163, 259-268, as applied to claims 1, 45 and 46 above, in view of Levy, et al. (hereinafter referred to as Levy) in view of *J. Exp. Med.*, 1988, 168, 475-489. Claims 13-21, 47, 48 and 52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shapiro in view of *Journal of Immunology*, 1999, 163, 259-268, in view of Levy in view of *J. Exp. Med.*, 1988, 168, 475-489, as applied to claims 2, 3, 5-7, 9, 10 and 37 above, and further in view of Smigielski, et al. (hereinafter referred to as Smigielski) in view of *Nucleic Acids Research*, 2000, 28(1), 352-355. Applicant respectfully submits that claims 2-3, 5-7, 9-21, 37-38, 45-48, 52-53 and 56-57, as amended, are patentable over the cited references for at least the reasons described below.

Claims 1 and 203-204

First, applicant respectfully submits that Shapiro does not disclose, teach or suggest “calculating a variation frequency **from a first base to a second base** within a group of bases in a dataset of two or more genes” as recited in claims 1 and 203-204. (emphasis added). As shown in Tables I-III, Shapiro discloses a mutability index for dinucleotides (Tables I and III) and trinucleotides (Tables II and III) for a first base, but does not disclose or take into consideration what the second base is. In other words, Shapiro calculates a mutability index for the first base without regard for what the second base is. As a result, applicant respectfully submits that Shapiro does not disclose, teach or suggest every element of the claimed invention as required by 35 U.S.C. § 103.

Second, applicant respectfully submits that Shapiro does not disclose, teach or suggest “generating a variation predictiveness matrix from the calculated variation frequency **for each first base to each second base**” as recited in claims 1 and 203-204. (emphasis added). As shown

in Tables I-III, Shapiro discloses a mutability index for dinucleotides (Tables I and III) and trinucleotides (Tables II and III) for a first base, but does not disclose or take into consideration what the second base is. In addition, Table III in Shapiro can be said to disclose a matrix, but the matrix is based on the position within the dinucleotide or trinucleotide. In other words, Shapiro's matrix is based on the position within the dinucleotide or trinucleotide without regard for what the second base is. As a result, applicant respectfully submits that Shapiro does not disclose, teach or suggest every element of the claimed invention as required by 35 U.S.C. § 103.

Third, applicant respectfully submits that Shapiro does not disclose, teach or suggest “comparing the ***nucleic acid sequence which is not obtained from the dataset of two or more genes***, one or more bases in the nucleic acid sequence at a time, with the variation predictiveness matrix to assign a variation value to the one or more bases in the nucleic acid sequence” as recited in claims 1 and 203-204. (emphasis added). As discussed above, the claimed variation predictiveness matrix is not identical to any matrix disclosed in Shapiro. In addition, Shapiro appears to be directed at one dataset at a time containing known mutations (page 260, Sequence Sources; Figures 1-7; Tables I-III) in order to determine whether “all Ig genes in mice and humans mutate by a common mechanism and that di- and trinucleotide sequence composition alone can predict regional mutation patterns, but in a nonquantitative manner” (page 260, left column, lines 14-17; Tables I-III). Applicant respectfully submits Shapiro does not use a variation predictiveness matrix determined for a dataset to analyze a nucleic acid sequence which is not obtained from that same dataset. As a result, applicant respectfully submits that Shapiro ***does not identically disclose*** every element of the claimed invention as required by 35 U.S.C. § 103.

Fourth, applicant respectfully submits that Shapiro does not disclose, teach or suggest “***identifying the locations of the one or more bases in the nucleic acid sequence where single nucleotide polymorphisms will likely occur*** based on the assigned variation value” in claims 1 and 203-204, or “outputting the ***identified locations of the single nucleotide polymorphisms in the nucleic acid sequence where single nucleotide polymorphisms will likely occur*** to a user via a computer display, an electronic file or a printer” as recited in claim 1. (emphasis added). As discussed above, Shapiro appears to analyze one data set at a time. Moreover, Shapiro only discloses mutability indexes and regional mutability (Tables I-III; Figures 3-6). Applicant respectfully submits that regional mutability is not identical to identifying the ***locations of bases*** where single nucleotide polymorphisms will likely occur. As a result, applicant respectfully submits that Shapiro does not disclose, teach or suggest every element of the claimed invention as required by 35 U.S.C. § 103.

With respect to Levy, applicant respectfully submits that Levy does not cure all the deficiencies of Shapiro, and there is no motivation based on the purposes stated in the references to combine them. For example, Levy does not determine a variation frequency or a variation predictiveness matrix; instead Levy compares sequences to a consensus sequence. (Figure 1). Moreover, Levy only appears to analyze heavy and light genes from the same type of lymphoma. (page 485, first two paragraphs). As a result, applicant respectfully submits that Shapiro and Levy, either alone or in combination, do not disclose, teach or suggest every element of the

claimed invention as required by 35 U.S.C. § 103. Accordingly, applicant respectfully submits that claims 1 and 203-204 are, therefore, allowable over Shapiro in view of Levy.

With respect to Lippa, applicant respectfully submits that Lippa does not cure all the deficiencies of Shapiro or Levy, and there is no motivation based on the purposes stated in the references to combine them. For example, Lippa does not determine a variation frequency, a variation predictiveness matrix, or identify the locations of bases where single nucleotide polymorphisms will likely occur. (see Table 1). Moreover, Lippa only appears to analyze Presenilin and Amyloid Precursor Protein Genes. As a result, applicant respectfully submits that Shapiro and Levy and Lippa, either alone or in combination, do not disclose, teach or suggest every element of the claimed invention as required by 35 U.S.C. § 103. Accordingly, applicant respectfully submits that claims 1 and 203-204 are, therefore, allowable over Shapiro in view of Lippa.

For at least these reasons, Shapiro and Levy and Lippa, either alone or in combination, do not disclose, teach or suggest every element of the claimed invention. Accordingly, applicant respectfully submits that claims 1 and 203-204 are not obvious over the cited references and are, therefore, allowable under 35 U.S.C. § 103(a). Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1 and 203-204.

Claims 2-3, 5-7, 9-21, 37-38, 45-48, 52-53 and 56-57

Applicant respectfully submits that claims 2-3, 5-7, 9-21, 37-38, 45-48, 52-53 and 56-57 depend from claim 1, which is allowable for the reasons stated above, and further distinguish over the cited references. Claims 2-3, 5-7, 9-21, 37-38, 45-48, 52-53 and 56-57 are, therefore, allowable under 35 U.S.C. § 103(a). Accordingly, applicant respectfully requests reconsideration and withdrawal of the rejection of claims 2-3, 5-7, 9-21, 37-38, 45-48, 52-53 and 56-57.

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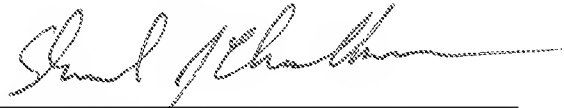
Appl. No. 09/998,904
Amdt. dated Feb. 17, 2009
Reply to Office Action of Aug. 14, 2008

Conclusion

For the reasons set forth above, applicant respectfully requests reconsideration by the examiner and withdrawal of the rejections. Applicant submits that claims 1-3, 5-7, 9-42, 44-53, 56-57 and 203-204, as amended, are fully patentable. Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If the examiner has any questions or comments, or if further clarification is required, it is requested that the examiner contact the undersigned at the telephone number listed below.

Date: February 17, 2009

Respectfully submitted,
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